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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

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SAIDHA, TEKCHAND	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 08/978,607
Filing Date: November 26, 1997
Appellant(s): FASTREZ ET AL.

William L. Strauss
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 4, 2005 (hereinafter, the Brief).

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

S.O.C

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

It is noted on page 5 of the Brief, Appellants state that currently no other appeals or interferences, of which Appellants, Appellants legal representative or Assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of the claims contained in the brief is substantially correct. The changes are as follows: Claim 24, which limits the starting enzyme to β-lactamase is enabled and described so as to satisfy the enablement and written description requirement under 35 U. S. C. § 112. Therefore the revised status of the claims is as follows:

Allowed claims: 30-35 and 37-38
Claims objected to: 24
Claims rejected: 13-23 and 25-29.

Claims cancelled: 1-12 and 36.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The subject matter of the 'Summary' by itself is accurate.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

(a) Having considered Applicants' arguments and amendments to the claims, claims 13 and 20 are not anticipated by Benito et al., J. Biol. Chem. 271: 21251-21256 (1996) or Brennan et al., Protein Engineering 7: 509-514 (1994), and rejections under 35 U. S. C. § 102 (a) and 35 U. S. C. § 102 (b) are withdrawn.

(b) The rejection of claim 24 under 35 U. S. C. 112, first paragraph, for lack of enablement is withdrawn because the method of claim 24 has the limitation, wherein the starting enzyme is β-lactamase, the specific enzyme bearing reasonable homology among different species, and is unlikely to substantially alter its suitability for use within the method, is therefore enabled.

(7) Grouping of Claims

The rejection of claims 13-29 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Benito et aI., J. Biol. Chem. 271: 21251-21256 (1996). (Cited by Appellants in Brief).

Brennan et al., Protein Engineering 7: 509-514 (1994). (Cited by Appellants in 'Brief').

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) Claims 13-23 and 25-29 are rejected under 35 U.S.C. 35 U.S.C. § 112. This rejection is set forth in a prior Office Action, mailed on July 30, 2003 ('Advisory Action'). As stated therein the disclosure of the instant application is enabling only for claims limited to a method of determining the amount of an analyte in a test sample using a chimeric β-lactamase as the starting enzyme, and comprising selected amino acids sequence insert in the loop of the rim of the active site residues 103-

105, for example; or the alpha. 11 helix residues 271-272 of the R-Tem β-lactamase, for example; in order that the enzyme be defined as a chimeric enzyme, which are then selected for binding by antibodies psa10 and psa66. The claims are directed to a method of determining the presence of an analyte using any (a) chimeric enzyme as the starting enzyme, wherein said chimeric enzyme is constructed by inserting a sequence of said mimotope (binding site moiety) into a sequence of said starting enzyme by replacing at least one amino acid of the starting enzyme with a sequence of said mimotope. However, the guidance provided for a single site specific chimeric β-lactamase is inadequate for one skilled in the art to develop a method using any chimeric enzyme construct for determining the presence or amount of an analyte in a test sample. Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988) [*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the

breadth of the claim. The factors most relevant to this rejection are the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

The claims are directed to a method for determining the presence of an analyte in a test sample using any enzyme as the starting enzyme, modifying the enzyme(s) to create a functional or enzymatically active chimeric enzyme having a binding site moiety, to which a binding molecule can attach. From the guidelines provided for construction of chimeric β-lactamase and the skill of the artisan in the area of molecular biological and enzymology it would have been possible to modify the mimotope as evidenced by SEQ ID Nos. 1-78 which is inserted by replacing at least a single amino acid in the chimeric β-lactamase structure from any source in order to selectively modulate the catalytic activity of the β-lactamase upon binding. Selective insertion sites have been identified, for example, the loop preceding the alpha -11 helix (residues 271-272 of β-lactamase.

However, the transfer of such a construct to any enzyme from any source in order to first produce a chimeric enzyme and further attempt to selectively insert mimotopes pertinent to any enzyme in order to create a chimeric enzyme which can successfully attach itself to a binding molecules and use

claimed assay or method, lacks adequate guidance, is unpredictable and would result in undue experimentation. It lacks adequate guidance because the chimeric insertion developed for β-lactamase by insertion of the specific mimotopes to achieve binding in β-lactamase may not necessarily function with any enzyme and such a binding function for determining the presence or amount of an analyte in a test sample is neither exemplified nor is a matter of routine experimentation. This is because the modification of mimotope amino acid(s) and its insertion into any enzyme, including those not characterized yet will not necessarily result in producing an active chimeric enzyme in every other enzyme because every other enzyme is distinct in its sequence, regions of active site or susceptibility to modifications, leading to highly unpredictable results. Thus, the specification fails to provide guidance to the claimed method employing any enzyme, other than β-lactamase modified at the specific positions, that can be successfully utilized in effectively creating chimeric enzymes and the appropriate steps required for such constructs. Every enzyme being distinct, it remains unpredictable that the instant disclosure on β-lactamase be sufficient to develop a method for determining analytes using other any chimeric enzyme or any sequence insert (Claim 13), which can successfully attach itself

to any binding molecules (claims 14-19), or where the analyte and substrate contact the enzyme simultaneously or in method steps (claims 20-23 and 25), or where the test sample contains the analyte (claim 25) or where the mimotopes is any one of the sequences of SEQ ID NOS : 1-78 (claims 26-27) or where the enzyme activity of the chimeric enzyme is in the unbound state (claims 28-29). Therefore, the skilled artisan would require guidance, such as the (a) the sequence of the β-lactamase (SEQ ID NO:) or the other chimeric enzymes (by SEQ ID Nos:) and guidance to where the sequence inserts of the mimotope (BSM) can be made, identification of the active catalytic and binding sites and the effect(s) of such modifications on the functionality of the different enzymes constructs, in order to make and use chimeric enzymes in a manner commensurate with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue

(11) Response to Arguments

It is noted that most, if not all of Appellants' arguments presented in this brief are new. Accordingly, the Examiner's response is made to address these arguments.

Appellants respectfully traverse the rejection and argue that the Examiner is actually rejecting claims 13-29 as allegedly not being enabled because he contends that undue

experimentation would be required in order to make the entire scope of the chimeric enzymes that might be used in the claimed methods. But the law requires only that the Appellants enable the claimed invention, not other inventions that might be useful in practicing the claimed invention. See M.P.E.P. § 2164, see also Phillips Petroleum Co. F. U.S. Steel Corp., 673 F. Supp. 1278, 6 U.S.P.Q.2d 1065 (D. Del. 1987), aff'd, 865 F.2d 1247, 9 U.S.P.Q.Zd 1461 (Fed. Cir. 1989). Here, the claimed invention is an assay method and that method is enabled by the specification. The claims do not encompass chimeric enzymes, which, if novel in a particular case, would be separately patentable.

As indicated here, claims 13-23 and 25-29 are rejected under 35 U.S.C. 35 U.S.C. § 112. Rejection of claim 24 under 35 U.S.C. 35 U.S.C. § 112 has been withdrawn, as explained in item 6. Appellants further argue that the law requires that the Appellants enable the claimed invention (only), not other inventions that might be useful in practicing the claimed invention. In explaining further, Appellants argue that 'the claimed invention' is an assay method and that method is enabled by the specification. Further explanation on page 12-14, is very vague, and in general terms, such as 'one skilled in the art, guided by the specification (see 'Brief', page 12, lines 1-3, page 12, 10-12, for example).

Appellants' argument that the claims do not require chimeric enzymes is not correct. Claim 13, lines 1-4, clearly state that the method requires a chimeric enzyme comprising a starting enzyme (which may be any enzyme) and a mimotope, for example. As far as claiming the chimeric enzyme separately, Applicants have already done so in **U. S. Patent 6, 500, 660**, wherein the broadest claim is drawn to " a chimeric β-lactamase enzyme comprising a β-lactamase and a mimetope inserted into or inserted by replacing at least one amino acid thereof, where said β-lactamase has the enzymatic activity which is modulated upon binding……".

Appellant's citation of M.P.E.P. § 2164, or case law - Phillips Petroleum Co. F. U.S. Steel Corp., 673 F. Supp. 1278, 6 U.S.P.Q.2d 1065 (D. Del. 1987), without substantiating its relevance to this rejection do not carry much weight (*see* Brief, page 11, 2nd paragraph). For example, Phillips Petroleum Co. F. U.S. Steel Corp., 673 F. Supp. 1278, 6 U.S.P.Q.2d 1065 (D. Del. 1987), dealing with adequacy of disclosure, wherein the application for patent of crystalline polypropylene which enabled person skilled in the art to make normally solid polypropylene consisting of recurring propylene units, and having substantial crystalline polypropylene content is not rendered non-enabling. How this analogy between a cited case

versus the instantly appealed case involving a method utilizing a range of enzyme modifications which is known to involve a high amount of unpredictability, is of relevance? Clearly, such a random citation of case law without due explanation of its relevance as it relates to the instant rejection is not very effective in understanding Appellants point of view. Therefore, Appellants' mere citation of the two Court decisions and MPEP does not explain their applicability to the instant claims. The Examiner is unclear as to their applicability and cannot answer these arguments further.

Appellants further argue that one skilled in the art, guided by the specification, could use the claimed methods without undue experimentation to perform the full scope of the assays encompassed by the claims. The specification provides both general guidance and specific examples for all necessary steps. Figures 4 and 5 show the entire assay method.

In these figures, a measurable signal (in this case, enzyme activity (Kcat)), is shown as a function of analyte concentration (in this case, PSA antibody concentration), thereby measuring the presence or amount of the analyte. Example 4 describes another specific example, where the analyte of interest was biotin. Thus, in contrast to the Examiner's

assertion that ''. . . such a binding function for determining the presence or amount of an analyte
in a test sample is neither exemplified nor is a matter of routine experimentation '' Advisory Action, page 4, line 5, the specification provides three specific examples. One skilled in the art would readily appreciate that the assay for PSA antibodies could easily be converted into an assay for PSA itself, which would block antibody binding to the chimeric enzyme.

Clearly Appellants citation of portion (one line) of 'Advisory Action', page 4, line 5, is misinterpreted. Advisory Action, dated 7/30/2003, lines 4-8 is reproduced here as follows:

"It lacks adequate guidance because the chimeric insertion developed for β-lactamase by insertion of the specific mimotopes to achieve binding in β-lactamase may not necessarily function with any enzyme and such a binding function for determining the presence or amount of an analyte in a test sample is neither exemplified nor is a matter of routine experimentation."

Based upon the actual reproduction of the entire sentence from the Advisory Action, it is amply clear that Appellants' inferences are not correct and are derived by fragmenting a

clear sentence to mean what the Appellants think would be suitable to them in this appeal process.

Further in response, it must be pointed out that Appellants have failed to address the key issues of the rejection.

For example, sequence homology or conservation of sequence homology is relied upon in order to evaluate how certain amino acid changes would effect or alter the enzyme activity. In the instant case, for example, if an amino acid change is made in the structure of a specific β-lactamase at a specific position to obtain a chimeric β-lactamase, the same change and effect may be difficult to reproduce in another species of β-lactamase with a different structure, and even more difficult to obtain in another enzyme or protein or starting molecules, such as a transferase, an oxido-reductase, subtilisin, alkaline phosphatase, etc., having an entirely different structure or sequence. While it is known that many amino acid substitutions or replacement are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, catalysis and in providing the correct three-dimensional spatial

orientation of binding and catalytic sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions. However, applicants have provided little or no guidance beyond the mere presentation of specific sequence inserts in β-lactamase to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in any enzyme (or protein) which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Such a definition might also read on previously characterized proteins, or alternatively, might include proteins with additional functions or activities neither envisioned nor enabled by applicants in the current invention. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988) with regard to the issues raised above.

In discussing Wands, Appellants argue that Examiner has considered only three of the Wands factors that he considered most relevant to this rejection, viz., the quantity of experimentation necessary, the amount of direction or guidance presented, and the predictability or unpredictability of the art (Advisory Action at 3).

In response it is stated that it is not necessary to address every Wands factor (see MPEP § 2164.01(a), for example). While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact.

Appellants further argue based upon the Wands factors that the specification describes (c) 5 libraries of recombinant bacteriophage β-lactamase chimeras with mimotopes inserted at several sites; (d) 50,000,000 clones transformed with short β-lactamase insertion sequences and selective sites; (e)State of the art describing epitopes and not mimotopes [see Benito et al., for example]; (f) a skilled artisan have a Ph.D. or other advanced degree; (g) breadth of the claim - 'assays for a large number of analytes of interest; and (a, b & g) considered by the

examiner, which includes, (a) The quantity of experimentation, (b) The amount of Direction or Guidance, and (g) the predictability or unpredictability of the art; and that the various wands factors clearly support the conclusion that the claimed invention is fully enabled by the specification, and the rejection of claims 13-29 under 35 U. S. C. § 112, first paragraph, as allegedly not being enabled by the specification is incorrect and should be withdrawn.

In response, it must be pointed out that Appellants have clearly misinterpreted the Wands factors in relation to what is enabled by the instant specification. Contrary to Appellants' arguments, it is clear that all the guidance, exemplification, etc., provided in the specification relate to an assay method utilizing **β-lactamase** chimeras with mimotopes inserted at specific insertion sites of the β-lactamase enzyme from *E. coli*. Perhaps, based upon the guidance, one skilled in the art may be able extrapolate the assay method to any β-lactamase from any source, but by no means to any enzyme available on this planet.

For the above reasons, it is believed that the rejection should be sustained.

(12) Grounds of Rejection

Claims 13-23 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is set forth in a prior Office Action, mailed on July 30, 2003 ('Advisory Action').

As stated therein, claims 13-29 are directed to a method of determining the amount of analyte in a sample using any chimeric enzyme or 'the claimed genus' from any organism wherein any of the amino acid residues along the peptide chain is modified to make chimeric enzyme. The specification describes amino acids inserts in the loop of the rim of the active site residues 103-105, for example; or the alpha. 11 helix residues 271-272 of the R-Tem β-lactamase, for example; in order that the enzyme be defined as a chimeric enzyme, which are then selected for binding by antibodies psa10 and psa66. The prior art teaches the R-Tem β-lactamase amino acid sequence which forms the reference or the base structure of the chimeric β-lactamase. The specification does not describe a representative number of species to the genus. A 'representative number of species' requires that the species which are expressly described be representative of the entire genus. Thus, when there is substantial variation within the genus, it may require a

description of the various species which reflect the variation within the genus. In the instant case, however, the description of a single species of the chimeric β-lactamase is not representative of the entire genus which includes any of the other enzyme(s), as the various species reflect variation within the genus. Therefore, if a specific amino acid site is altered in a β-lactamase enzyme, without a clear description of the identities of equivalent site of β-lactamase from other species, such a alteration or modification may not result in having a similar effect in any genus or species claimed. What constitutes a 'representative number' is an inverse function of the predictability of the art. The number must be sufficient to identify the other members of genus. In an unpredictable art, such as the instant one, wherein a chimeric β-lactamase enzyme is made by insertion of specific mimotopes (SEQ ID NO : 1-78), adequate written description requirement of a genus cannot be achieved by disclosing only one species (β-lactamase) within the genus. In such a case, where the members of the genus being claimed are expected to vary widely in their identifying characteristics, such as structure or enzyme activity, due to the introduced changes in the mimotope sequence to alter a particular enzyme property, for example, binding, written

description for each member within the genus will be necessary. Therefore, the written description requirement is not satisfied.

(13) Response to Arguments

It is noted that most, if not all of Appellants' arguments presented in this brief are new. Accordingly, the Examiner's response is made to address these arguments.

As indicated here, claims 13-23 and 25-29 are rejected under 35 U.S.C. 35 U.S.C. § 112. Rejection of claim 24 under 35 U.S.C. 35 U.S.C. § 112 has been withdrawn, as explained in item 6.

Appellants argue that according to the Examiner claims 13-29 are directed to a method of determining the amount of analyte in a sample using any chimeric enzyme or the claimed genus. The Examiner also asserts that a representative number of β-lactamase species are not described in the application as filed. *See* Advisory Action at 9-10. (*See* Brief, page 19, 1st paragraph).

Appellants further argue that - "Again however, the claimed invention is neither chimeric enzymes generally nor chimeric enzymes derived from β-lactamase. (*See* Brief, page 19, 2nd paragraph).

Appellants contradict their first statement with the second. As presented above Appellants argue that (1) according to the Examiner claims 13-29 are directed to a method of

determining the amount of analyte; and then argue that (2) the claimed invention is neither chimeric enzymes generally nor chimeric enzymes derived from β-lactamase.

Which one is it? The rejection clearly addresses 'the method' utilizing the 'chimeric construct(s)'. In order that the method be described, all the elements or the product(s) required to carry out the method must be also described. In the instant case the 'chimeric construct' used in the method is key for the method to be functional and is not described in the specification to the extent required in order to meet the written description requirement as explained above. This is supported by the decision of the following CAFC case, which is briefly described.

See University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 CAFC 2004), wherein, "A method patent for treating the side effects of pain relievers is invalid for failing to adequately describe the compound used in the claimed method, the U.S. District Court for the Western District of New York rules. Granting a summary judgment motion, the court reasons that the written description requirement of 35 U.S.C. §112 ¶1 cannot be satisfied by merely providing the desired function of the compound without more detail on the compound's structure, chemical formula, chemical name, or physical properties. The

court also stresses the applicability of the written description requirements to the compound used, even though the patent consists of method claims rather than compound claims.

Appellants argue (*see* Brief, page 19, 3rd paragraph), "to support his position, the Examiner cites the specification at page 2, lines 10-12 for the proposition that "Applicants further argue that the invention is to a 'desired target (TM) which can be modified to have at least one binding site moiety (BSM) to which a binding molecule can attach." As an initial matter, the cited portion of the specification does not state that the invention is to a desired target molecule. Rather, the specification does not state that "In accordance with the present invention, a desired target molecule ™ can be modified..." Moreover, even if the Examiner's assertion were correct, this is not the invention claimed.

In response, it must be clarified that at the beginning of the enablement and written description rejections - it was clearly stated that the claims are "method claims" and nothing but "method claims". Since further elements of the method claims encompass, for example, 'the chimeric enzyme', or 'target molecule' (TM), etc., a discussion of these method elements in these rejections, does not means that the claim(s) or invention is drawn to these elements. It is very likely that the

Appellants will understand this basic point(s). Further, it is not clear what the Appellants' is trying to achieve by repeating their incorrect interpretation, pertaining to the elements of the method claims, viz., 'this is not the claimed invention' (*See* Brief, page 19 last paragraph, page 20, lines 1-2).

Appellants argue that Examiner's position is akin to asserting that hypothetical claims to a novel immunoassay method would not be adequately supported unless the accompanying specification describes a representative number of antibodies that could be used in the assay. This is not the law. All that is necessary to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, is that the specification convey to one skilled in the art that the applicants were in possession of the claimed invention at the time of filing. See Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

In response it is stated that Appellants generalization of Examiner's positions as being akin to asserting that hypothetical claims to a novel immunoassay method would not be adequately supported unless the accompanying specification describes a representative number of antibodies that could be used in the assay, is not correct, because the fact pattern of every case may not be the same, and determination of what is

sufficiently described in this case has been made based on the fact pattern of this case.

Appellant's claimed invention is an assay method, argues Appellants (*See* Brief, page 20, 2nd paragraph and foot note). As described above, the specification presents three specific examples of the claimed assays: two for PSA antibodies and one for biotin. See Example 3-4. Because the percent inhibition of the chimeric enzyme activity depends on the amount of anti-PSA antibody bound, one skilled in the art would immediately understand that the chimeric enzymes could be used in an assay to detect an analyte, prostate specific antigen, that would block antibody binding. The specification also describes libraries of recombinant bacteriophage from which chimeric enzymes useful in practicing the claimed assay methods for other analytes can be harvested. See Example 2. No one could seriously doubt that Appellants were in possession of the entire scope of the claimed assays.

As per the method claim 13, for example, detection of the amount of catalysis of the substrate is used for determining the presence or absence of the analyte of interest. Catalysis of the substrate is accomplished by the using chimeric β-lactamase as the starting enzyme. Because the percent inhibition of the chimeric enzyme activity depends on the amount of anti-PSA

antibody bound to the mimotope of the chimeric β-lactamase, such a functionality may not achieved with any enzyme, because no description is provided in the specification for the insertion of the β-lactamase specific mimotopes into any enzyme construct such as those claimed as possible target molecules on pages 5 and 6 of the instant specification, viz., plasmin, prostate specific antigen, subtilisin, trypsin, alkaline phosphatase, β-galactosidase, staphylococcal nuclease, glutathione transferase, lysozyme, and catalytic antibodies. Based upon the instant disclosure, it would be impossible to determine where the specific mimotopes inserted into β-lactamase sites to create the chimeric β-lactamase, would be inserted into every other enzyme? Will the same mimotope sequences (SEQ ID Nos. 1-78) identified for create chimeric β-lactamase(s) be effective as mimotopes insertions into any enzyme? The specification is silent about describing constructs that can be employed in the claimed method. Applicants' mention in the passing of possible target molecules on pages 5 and 6 of the instant specification, is not considered to sufficiently describe the claimed genus.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Tekchand Saidha
Primary Examiner, Art
Unit 1652

June 17, 2005

Conferees
P. Achutamurthy & John Weber

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
[Conferee]

JON WEBER
SUPERVISORY PATENT EXAMINER